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Serial No. 10/768,972: Hip Prosthesis

Hip Prosthesis

The invention relates to a hip prosthesis for implantation in humans and animals.

Known hip prostheses comprise a shaft which is implanted in the femur, and a ball head which is anchored to the shaft by a conical clamp, for example. The ball head rotates in a socket. The socket may be implanted directly in the acetabulum, or may be inserted in an additional outer shell or in plastic sheathing and then implanted.

In the known hip prostheses, a certain tendency toward luxation is always observed; i.e., for certain motions the ball head slides out of the socket. In the medical literature, the percentage tendency for luxation of prosthetic systems such as hip prostheses is in the single digits.

This tendency toward luxation could be counteracted by a raised edge on the socket, or by increasing the slide pairing diameter. The slide pairing diameter of the ball head is determined by the diameter of the outer surface of the ball head which articulates with the socket.

However, various disadvantages result from these structural designs. For example, a raised edge on the socket severely limits the range of motion of the ball head with the shaft in the socket. The use of larger slide pairing diameters, i.e., a larger ball head and a larger socket, is limited by restrictions on the available space.

The object of the invention is to improve the tendency toward luxation in hip prostheses, compared to the prior art.

This object is achieved according to the invention by placing a bipolar shell between the ball head and the socket, whereby the ball head rotates in the bipolar shell and the bipolar shell rotates in the socket. The luxation is greatly reduced by this doubled capability for rotation. This system is also referred to as a "double mobility system."

The ratio of the diameters of the slide pairing of the bipolar shell and the ball head preferably is between 1.05 and 5, preferably between 1.2 and 2.

The slide pairing diameter of the bipolar shell is advantageously between 26 mm and 40 mm, preferably 32 mm, and the slide pairing diameter of the ball head is between 14 mm and 32 mm, preferably 22.2 mm.

For a hip prosthesis having a ceramic ball head, a ceramic bipolar shell, and a ceramic socket, the tribological conditions of the ceramic components are advantageously defined by a combination of the following features:

a) The hardness of the ceramic components is greater than 1,000 HV (Vickers).

b) The surface finishes on the articulating surfaces of the ceramic components have a roughness less than 0.1 μm (Ra value < 0.1 μm).

c) The contact angle between the articulating surfaces of the ceramic components is between 1° and 8° (measured in Ringer's solution).

d) The difference in the slide pairing diameters of the articulating surfaces of the ceramic components is between 1 and 200 μm, preferably between 20 and 120 μm.

In one preferred embodiment the centers of rotation of the ball head with respect to the bipolar shell, and of the bipolar shell with respect to the

socket, have an offset d which is between 0.1 mm and 5 mm, preferably between 1.5 and 2.5 mm.

In a further preferred embodiment the bipolar shell in cross section has different wall thicknesses, the greatest wall thickness being provided in the region of the opening.

The ball head is held in the bipolar shell by a retaining ring inserted into the bipolar shell at the edge of same.

The advantages of this hip prosthesis are described below in comparison to the prior art.

- The range of motion (ROM) is greatly increased compared to systems with a banked socket edge.
- The tendency toward luxation is greatly reduced by a wedging effect between the bipolar shell with the retaining ring, and the socket.
- The specialized kinematics and tribology result in a motion that is different from simple rotation.

The sequence of motion is as follows:

First there is motion between the ball head and the bipolar shell. If the range of motion of this first sliding surface is expended, for example by the shaft striking against the retaining ring, the second sliding surface between the bipolar shell and the socket is deployed; i.e., the further motion occurs only at the outer sphere of the bipolar shell.

As a result of the defined tribological properties and kinematic conditions, there is no pure rotation about the midpoint of the outer sphere of the

bipolar shell, but instead, next there is rotation of the bipolar shell about the midpoint of the ball head. The bipolar shell rotates out of the socket. As a result of this specialized coupled motion there is a wedging effect between the bipolar shell with the retaining ring, and the socket. Luxation is thus made much more difficult, as shown by measurements of the luxation force. As a result, the tendency toward luxation is considerably lower.

Materials of the Prosthetic System:

The prosthesis may be composed of the following materials:

1. Prosthesis shaft (metal, ceramic, plastic), preferably metal

2. Ball head (ceramic, metal, plastic), preferably ceramic

3. Bipolar shell (metal, ceramic, plastic), preferably ceramic

4. Retaining ring (metal, ceramic, plastic), preferably plastic

5. Socket or socket insert (metal, ceramic, plastic), preferably ceramic

Further features of the invention become evident from the figures described below:

Figure 1 shows the end of shaft 1 which faces the ball head;

Figure 2 shows a ball head 2;

Figure 3 shows a bipolar shell 3;

Figure 4 shows a retaining ring 4 for insertion in bipolar shell 3;

Figure 5 shows a socket 5;

Figure 6 shows a hip prosthesis; and

Figure 7 shows a hip prosthesis with offset d indicated.

Figures 1 through 5 show in cross section the individual parts of an inventive embodiment of a hip prosthesis, and Figures 6 and 7 show a cross section of a complete hip prosthesis.

Figure 1 shows the front part of a shaft 1, which with its end not shown is implanted in the femur. The end of shaft 1 shown is provided with a conical surface 7. This conical surface 7 is used for affixing a ball head 2, as shown in Figure 2. Ball head 2 has a recess, likewise provided with a conical surface on its circumferential surface, so that ball head 2 can be affixed to shaft 1.

Figure 3 shows a bipolar shell 3 with a spherical outer surface 9. In the interior of bipolar shell 3, on its side facing the opening, a recess 8 is provided in which a retaining ring 4 (see Figure 4) can be inserted. This retaining ring 4 is used for affixing ball head 1 in bipolar shell 3.

Figure 5 shows a socket 5 having a spherical recess which is used to accommodate the bipolar shell shown in Figure 3. Socket 5 is provided on its outer side with a conical slope 10 which transitions via two flat regions 11, 12 into a flat region 13 running parallel to upper edge 14.

Figures 6 and 7 show the assembly of the referenced individual components.

In this preferred embodiment, shaft 1 is made of metal (titanium), and ball head 2, bipolar shell 3, and socket 5 are made of ceramic, which are specially processed or manufactured as described above. Outer shell 6 in which socket 5 is inserted is made of metal. This shell 6 may optionally be omitted when socket 5 is implanted directly in the acetabulum. The retaining ring indicated by reference number 4 is made of plastic.

Figure 7 shows offset d of the centers of rotation of ball head 2 – bipolar shell 3 and bipolar shell 3 – socket 5.